

UNITED STATES PUBLIC HEALTH SERVICE TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 206

PHS Policy Regarding Infringement of Government-Owned Inventions

A. PURPOSE

This Manual Chapter establishes the policy for identifying and acting upon allegations of infringement of patents in which the U.S. Government has an ownership interest and which are administered by the Public Health Service (PHS), which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC).

B. BACKGROUND

The primary mission of PHS research laboratories is to pursue new knowledge through the conduct and support of research to improve public health. Pursuant to the Stevenson-Wydler Act of 1980 (PL 96-480) and the Federal Technology Transfer Act of 1986, as amended, Federal (PL 99-502), federal laboratories must strive, including PHS research laboratories at the National Institutes of Health (NIH), Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC) were given a statutory mandate to ensure that new technologies developed in federal laboratories are transferred to the private sector and commercialized in an expeditious and efficient manner.

The Government owns, in whole or in part, thousands of patents and patent applications covering the work of PHS inventors. This portfolio represents an investment of millions of dollars in securing the intellectual property rights and an even larger investment in the research that produced these innovations. The public investment in this portfolio reflects a determination that obtaining patent protection encourages the commercialization of inventions made in PHS laboratories.

The Government's ability to use its intellectual property portfolio as a tool to develop technology is diminished by infringement. First, infringement discourages the licensing and development of Government technologies if non-licensees can practice the invention without cost. Second, competition by infringers reduces sales of licensed products and the consequent royalty income to the Government. Third, infringement reduces the inventors' incentive to report inventions.

Diligent enforcement of patent rights deters infringement and encourages licensing of PHS technology. It is recognized, however, that in some cases, the high cost of litigation or the modest value of the technology outweighs the value of vigorous enforcement of patent rights.

C. POLICY

The policy of the PHS is to enforce its patents in the manner that the PHS believes is best suited to advance the mission of the agency. Toward this end, the PHS will, as appropriate, encourage alleged infringers to license or sublicense the technology, grant its licensees the right of enforcement as provided by 35 U.S.C. § 207(a)(2), or refer the matter to the Department of Justice for civil action.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter are effective June 17, 2010, and supersedes in its entirety the policy in PHS Technology Transfer Manual Chapter 206, which was first approved on November 9, 1995.

E. ADDITIONAL INFORMATION

For further information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057 or <http://www.ott.nih.gov/contact-us> .